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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,477	11/21/2003	Lieping Chen	07039-443001	3624

26211 7590 01/19/2007
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EXAMINER	
OUSPENSKI, ILIA I	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,477	CHEN ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-18 and 32-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment/remarks, filed 11/10/2006, are acknowledged.

Claims 1 – 39 are pending.

Claims 1 – 18 and 32 – 39 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 05/08/2006.

Claims 19 – 31 are under consideration in the instant application.

2. This Office Action will be in response to applicant's amendment and arguments, filed on 11/10/2006.

The rejections of record can be found in the previous Office Action, mailed on 07/10/2006.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

3. The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

4. Claims 19 – 31 stand rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 19 – 31 are indefinite in the recitation of "identifying a subject that is suspected of having, or is likely to develop, a disease," because the criteria for "identification" are unknown.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the instant claims are not limited to any range of methods of performing the relevant identification, and that those ordinarily skilled in the art would be familiar with the signs and symptoms exhibited by subject suspected of having the relevant diseases or conditions. Applicant cites an example of a subject undergoing transplantation procedures as being "likely to develop" graft rejection responses.

While it is acknowledged that with regard to graft rejection responses, one of ordinary skill in the art would be reasonably apprised as to the identification of subjects suspected of having, or is likely to develop, the condition, with respect to the other conditions within the scope of the claim the term "identifying" remains vague and indefinite.

B. Claims 19 – 24 are indefinite in the recitation of "an elevated level of one or more B7-H1-specific antibodies," because "elevated" is a relative term which renders the claim indefinite.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that a skilled artisan would understand the term "elevated" to mean "above normal."

This is not found persuasive, because one of ordinary skill in the art would not be reasonably apprised as to which of the plurality of possible "normal" levels to use, e.g. the level I same patient before the onset of the relevant symptoms; the average of the target patient population; or the average of the general population, etc. Likewise, what level of "elevation" is considered informative, as compared with normal variation within the respective population? A relative term line "elevated" renders the claim indefinite in the absence of a specific definition, or a standard for ascertaining the requisite degree of elevation or base level for comparison.

C. Claims 25 – 31 are indefinite in the recitation of "wherein the level of one or more B7-H1-specific antibodies in the sample correlates with the stage of the disease or pathological condition," because the phrase is vague and indefinite.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that those skilled in the art would know very well that such correlations are made by comparing the level of antibody in a subject with the levels of antibody in "standard" subjects having different defined stages of the disease or condition and would know how to perform studies to ascertain such "standard" levels. The level or amount of correlation will likely vary greatly from one disease or condition to another but will be readily ascertainable from the entirely routine studies mentioned above designed to obtain "standard" levels.

This is not found persuasive, because even if the methods in the art are routine, one of skill in the art requires specific guidance in the claims to ascertain which methods are within the scope of the instant claims.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

5. Claims 19 – 31 stand rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following *Written Description* rejection is set forth herein.

Applicant is not in possession of antibodies to a generically recited "human B7-H1."

Applicant's arguments have been fully considered but have not been found convincing.

Applicant has amended the claims to recite "human B7-H1," and provided a prior art reference (Dong et al., 1999, Nature Medicine, 5: 1365 – 1369) which discloses an amino acid sequence of human B7-H1 and polyclonal antibodies to this protein. Applicant further cites Falko-Gunter Falkner v Inglis to support the assertion that satisfaction of written description requirement does not require the recitation of sequences.

This is not seen as sufficient to overcome the rejection of record, because the scope of the recitation is not limited to a single sequence of human B7-H1. The instant specification discloses at pages 3 – 4, bridging paragraph, that polypeptides of the instant invention include variant polypeptides that are identical to corresponding wild-type polypeptides but differ by not more than 50 conservative substitutions. In the absence of sufficient structural and fictional description of the molecule, this definition is not seem as placing Applicant is possession of the claimed genus, because the skilled artisan cannot envision all the contemplated amino acid sequence possibilities encompassed by the instant claims.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

6. Claims 19 – 20, 24 – 27, and 31 stand rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention.

The specification does not provide a sufficient enabling description of the claimed methods of diagnosis, or of monitoring the progress, of a generically recited "disease or pathological condition" with symptoms caused by activation of T cells, or of "an autoimmune disease."

Applicant's arguments have been fully considered but were found only partially convincing.

Applicant relies on an evidentiary reference (Dong et al., of record) to argue that B7-H1-specific autoantibodies can be informative in diagnosing rheumatoid arthritis,

systemic lupus erythematosus, and autoimmune hearing loss. The rejection of record, as it pertains to these specific diseases, has been withdrawn in view of Applicant's amendment and arguments.

However, given the unpredictability of the art, which has been addressed in detail in the previous Office Action, the rejection of record is maintained for the reasons of record with regard to generic recitations of "disease or pathological condition" with symptoms caused by activation of T cells, and "an autoimmune disease."

7. Conclusion: no claim is allowed.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.
Patent Examiner
Art Unit 1644

January 16, 2007

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
1/16/07